K062324

DEC 26 2006

Premarket Notification 510(k) Summary
As required by section 807.92
MRI Monitor with L-CANE05 or L-CANE05A software, module options N-PSNGV, N-PSNG, N-SNGV, N-SNG, N-PSN, N-SN, E-MRICAiOVX, E-MRICAiOV, E-MRICAiO, E-MRICO and accessories

GENERAL COMPANY INFORMATION as required by 807.92(a)(1)

COMPANY NAME/ADDRESS/PHONE/FAX:

GE Healthcare
86 Pilgrim Road
Needham, MA 02492 USA
Tel: 781-449-8685
Fax: 781-433-1344

NAME OF CONTACT:

Mr. Joel Kent

DATE:

August 7, 2006

DEVICE NAME as required by 807.92(a)(2)

TRADE NAME:

The MRI Monitor with L-CANE05 or L-CANE05A software, module options N-PSNGV, N-PSNG, N-SNGV, N-SNG, N-PSN, N-SN, E-MRICAiOVX, E-MRICAiOV, E-MRICAiO, E-MRICO and accessories

COMMON NAME:

Patient Monitor

CLASSIFICATION NAME:

The following Class II and Class I classifications appear applicable:

Product Code	Classification Name	CFR Section
MHX	Arrhythmia detector & alarm	870.1025
MLD	Monitor ST-segment & alarm	870.1025
DSF	Paper Chart Recorder	870.2810
CCK	Analyzer, Gas, Carbon-Dioxide, Gaseous-phase	868.1400
CCL	Analyzer, Gas, Oxygen, Gaseous-phase	868.1720
BZK	Spirometer, Monitoring (W/WO alarm)	868.1850
CBR	Analyzer, Gas, Nitrous-Oxide,Gaseous-phase (Anesthetic co)	868.1700
BZL	Computer, Oxygen-uptake	868.1730
CBQ	Analyzer, Gas, Enflurane, Gaseous-phase (Anesthetic conc.)	868.1500
CBS	Analyzer, Gas, Halothane Gaseous-phase (Anesthetic conc.)	868.1500
NHO	Analyzer, Gas, Desflurane, Gaseous-phase (Anesthetic conc.)	868.1500
NHQ	Analyzer, Gas, Isoflurane Gaseous-phase (Anesthetic conc.)	868.1500
NHP	Analyzer, Gas, Sevoflurane,Gaseous-phase (Anesthetic conc)	868.1500
DQA	Oximeter	870.2700
DRT	Cardiac Monitor (including cardiotachometer and rate alarm)	870.2300
DPS	Electrocardiograph	870.2340
DXN	Non-invasive blood pressure measurement system	870.1130
DSK	Blood pressure computer	870.1110
DRQ	Transducer signal amplifier and conditioner	870.2060
DSA	Cable, transducer and electrode, Patient including connector	870.2900

NAME OF LEGALLY MARKETED DEVICE FOR WHICH A CLAIM OF SUBSTANTIAL EQUIVALENCE IS MADE as required by 807.92(a)(3)

The MRI Monitor with L-CANE05 or L-CANE05A software, module options N-PSNGV, N-PSNG, N-SNGV, N-SNG, N-PSN, N-SN, E-MRICAiOVX, E-MRICAiOV, E-MRICAiO, E-MRICO and accessories is substantially equivalent to the predicates D-E MRI Monitor (980651), S/5™ CAM with L-CANE05 and L-CANE05A (K061185), Datex-Ohmeda S/5™ E-CAiOVX Module (K051092) and accessories and Datex-Ohmeda S/5™ E-PRESTN Module (K051217) and accessories.

DEVICE DESCRIPTION as required by 807.92(a)(4)

The MRI Monitor has the following key components: MRI Shield in which the Compact Monitor Frame is placed, Monitor software and Built-in measurement modules. The optional components consist of Remote Controller, Anesthesia Record Keeper Keyboard and an aluminum/plastic MRI cart with locking casters.

The MRI Monitor can be controlled by the keys on the monitor's keyboard, Remote Controller or by Active Remote Screen keyboard. Function keys provide direct access to menu functions determined to be most important to the user. The ComWheel™ provides access to any menu function. The command board located on the lower front face of the monitor contains seventeen function keys, a wheel (ComWheel) for selection of monitor functions from menus as well as the on/off switch for the monitor. Function keys provide direct access to menu functions determined to be most important to the user. The ComWheelTM provides access to any menu function. There are keys on the monitor's side panel for ON/Standby, NIBP, Invasive Pressures and Recorder functions. With these keys, you can start or end a function immediately.

The built-in recorder is a thermal printer and records up to three real time waveforms simultaneously or displays recordings of numerical information in horizontal and vertical plane. The recorder prints up to 24 hours or graphical and numerical trend data.
The remote controller (K-CREMCO) has twelve function keys and a ComWheel for accessing all other monitor functions. It also has some direct function keys, which start or end a function immediately. To enter functions that do not have their own key, press the Menu key. The remote controller is not cordless but remains attached to the command board via a cable.
The anesthesia record keeper keyboard (K-ARKB) is attached to the frame with a cable. The record keeper keyboard features command board, record keeper function keys and letter and number keys (alphanumeric keys).
The bar code reader can be used to facilitate quick access to menus. The bar code reader is connected to the LCD display or to the record keeper keyboard. The manufacturing of the bar code reader has been discontinued, but the monitor software L-CANE05(A) still supports the use of it
The parameter modules for the MRI monitor are built into the Compact Monitor frame during manufacturing. They cannot be removed during monitoring. Depending on the configuration the MRI Monitor features a different set of parameters.

INTENDED USE as required by 807.92(a)(5)

Intended Use:
The MRI Monitor with L-CANE05 or L-CANE05A software, module options N-PSNGV, N-PSNG, N-SNGV, N-SNG, N-PSN, N-SN, E-MRICAiOVX, E-MRICAiOV, E-MRICAiO, E-MRICO and accessories is intended for multiparameter patient monitoring.

Indications for use:
The MRI Monitor with L-CANE05 or L-CANE05A software, module options N-PSNGV, N-PSNG, N-SNGV, N-SNG, N-PSN, N-SN, E-MRICAiOVX, E-MRICAiOV, E-MRICAiO, E-MRICO and accessories is indicated for monitoring of hemodynamic (comprising ECG (including heart rate, ST-segment and arrhythmia), NIBP, SpO2, and invasive blood pressure), respiration (CO2, O2, N2O, anesthetic agents, anesthetic agent identification and respiration rate) ventilation (airway pressure, volume and flow) and gas exchange (Oxygen Consumption VO2, Carbon Dioxide production VCO2, Respiratory Quotient RQ, and Energy Expenditure, EE, Gas exchange monitoring is not indicated in the presence of N2O+O2 mixtures), status of hospital patients during magnetic resonance scanning.
The NIBP measurement is indicated for patients who weigh 5kg (11 lb) and up. The MRI Monitor with L-CANE05 or L-CANE05A software is also indicated for documenting patient care related information.
The MRI Monitor with L-CANE05 or L-CANE05A software, module options N-PSNGV, N-PSNG, N-SNGV, N-SNG, N-PSN, N-SN, E-MRICAiOVX, E-MRICAiOV, E-MRICAiO, E-MRICO and accessories is indicated for use in the MR environment up to 300 Gauss with static magnets up to 3.0 Tesla. SpO2 and ECG monitoring is indicated only with accessories (OXY-FMR, OXY-WMR, 897986 (ECG cable, AAMI) and 897987, ECG Cable, IEC) specifically designed for the MR environment.
The MRI Monitor with L-CANE05 or L-CANE05A software is indicated for use by qualified medical personnel only.

SUMMARY OF TECHNOLOGICAL CHARACTERITICS OF DEVICE COMPARED TO THE PREDICATE DEVICE as required by 807.92(a)(6)

The MRI Monitor design follows similar principles as the predicate Datex-Engstrom MRI Monitor (K980362). The predicate Datex-Engstrom MRI Monitor (K980362) utilized the existing technology of Datex-Engstrom Compact Anesthesia Monitor and its modules of that time. These monitor components were placed in an RF Shield to eliminate the RF interference. The combination of the RF shield, the monitor frame and the parameter modules was called Datex-Engstrom MRI Monitor (K980362). The MRI Monitor has been designed in the same way. The existing technology of S/5 Compact Anesthesia Monitor with L-CANE05 and L-CANE05A software (K061185) and its parameter modules are placed in the new RF Shield. This combination of a RF shield, S/5 Compact Anesthesia Monitor and its parameter modules is called MRI Monitor. The main difference is in performance. The predicate Datex-Engstrom MRI Monitor (K980362) was intended for use in MRI room up to the 20 Gauss line. The 20 Gauss line specification does not allow the use of the predicate Datex-Engstrom MRI Monitor (K980362) close to the MRI system. It might degrade the MRI image quality due to the RF emissions. The new MRI Monitor is intended for use in the MRI Room up to the 300 Gauss line. This has been achieved by using a new RF shield, which eliminates the RF interference better than the predicate. Thus, the MRI Monitor can be closer to the MRI system giving more flexibility to move the MRI Monitor in and out of the MRI Room. The MRI Monitor uses the F-MRICM1, which is modified from the F-CM1 S/5 Compact Anesthesia Frame (K061185). The MRI Monitor with N-PSNGV option utilizes the technology of the Datex-Ohmeda E-PRESTN (K051217) modules. The MRI Monitor with E-MRICAiOVX option utilizes the technology of the Datex-Ohmeda E-CAiOVX (K051092) modules.

Based on the above analysis and a detailed analysis and other documentation included in this submission and attachments, it is evident that the main features and indications for use of the MRI Monitor with L-CANE05 or L-CANE05A software, module options N-PSNGV, N-PSNG, N-SNGV, N-SNG, N-PSN, N-SN, E-MRICAiOVX, E-MRICAiOV, E-MRICAiO, E-MRICO and accessories is substantially equivalent to the predicates D-E MRI Monitor (980651), S/5™ CAM with L-CANE05 and L-CANE05A (K061185), Datex-Ohmeda S/5™ E-CAiOVX Module (K051092) and accessories and Datex-Ohmeda S/5™ E-PRESTN Module (K051217) and accessories.

SUMMARY OF NONCLINICAL TESTING FOR THE DEVICE and CONCLUSIONS as required by 807.92(b)(1)(3)

The MRI Monitor with L-CANE05 or L-CANE05A software, module options N-PSNGV, N-PSNG, N-SNGV, N-SNG, N-PSN, N-SN, E-MRICAiOVX, E-MRICAiOV, E-MRICAiO, E-MRICO and accessories has been assessed against the standards below. The device has been thoroughly tested through validation and verification of specifications.

- FDA 21 CFR Part 898, § 898.12
- IEC 60601-1:1998, Amendment 1: 1991, Amendment 2: 1995
- EN60601-1:1990 Medical electrical equipment Part 1:General requirements for safety Amendment 1: 1993 Amendment 2: 1995, Amendment 13: 1996
- CAN/CSA - C22.2 No. 601.1-M90: Medical Electronical Equipment. Part 1: General requirements for safety + Supplement 1: 1994, Amendment 2: 1998
- UL 2601-1
- IEC 60601-1-2 / EN 60601-1-2
- IEC 60601-1-4:1996 / EN 60601-1-4, Amendment 1: 1999
- IEC 60601-2-49:2001
- EN 60601-2-49:2001
- IEC 60601-2-27 / EN 60601-2-27:
- IEC 60601-2-30 /EN 60601-2-30
- IEC 60601-2-34 / EN 60601-2-34
- ISO 7767 / EN 12598
- ISO 9918 / EN 864
- ISO 9919 / EN 865
- ISO 11196:1995 + Corr.1:1997 / EN ISO 11196:1997
- IEC 60068-2
- ANSI/AAMI ES-1: 1993
- FDA /ODE Guidance for Content of Premarket Submission for Software Contained in Medical Devices, May 11, 2005
- FDA Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm", Oct 28 2003
- ANSI/AAMI EC57:1998
- AAMI EC13-2002
- FDA GGP: A Primer on Medical Device Interactions with Magnetic Resonance Imaging Systems, CDRH Magnetic Resonance Working Group.

CONCLUSION:

The summary above shows that there are no new questions of safety and effectiveness for the MRI Monitor with L-CANE05 or L-CANE05A software, module options N-PSNGV, N-PSNG, N-SNGV, N-SNG, N-PSN, N-SN, E-MRICAiOVX, E-MRICAiOV, E-MRICAiO, E-MRICO and accessories as compared to the predicates D-E MRI Monitor (980651), S/5™ CAM with L-CANE05 and L-CANE05A (K061185), Datex-Ohmeda S/5™ E-CAiOVX Module (K051092) and accessories and Datex-Ohmeda S/5™ E-PRESTN Module (K051217) and accessories.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 6 2006

GE Healthcare
c/o Mr. Joel C. Kent
Manager, Quality and Regulatory Affairs
86 Pilgrim Road
Needham, MA 02492

Re: K062324
Trade Name: MRI Monitor with L-CANE05 or L-CANE05A software, module options N-PSNGV, N-PSNG, N-SNGV, N-SNG, N-PSN, N-SN, E-MRICAiOVX, E-MRICAiOV, E-MRICAiO, E-MRICO and accessories
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia detector and alarm
Regulatory Class: II
Product Code: MHX
Dated: October 24, 2006
Received: October 25, 2006

Dear Mr. Kent:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at 240-276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

B Zuckerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062324

Device Name: MRI Monitor with L-CANE05 or L-CANE05A software, module options N-PSNGV, N-PSNG, N-SNGV, N-SNG, N-PSN, N-SN, E-MRICAiOVX, E-MRICAiOV, E-MRICAiO, E-MRICO and accessories.

Indications for use:

The MRI Monitor with L-CANE05 or L-CANE05A software, module options N-PSNGV, N-PSNG, N-SNGV, N-SNG, N-PSN, N-SN, E-MRICAiOVX, E-MRICAiOV, E-MRICAiO, E-MRICO and accessories is indicated for monitoring of hemodynamic (comprising ECG (including heart rate, ST-segment and arrhythmia), NIBP, SpO2, and invasive blood pressure), respiration (CO2, O2, N2O, anesthetic agents, anesthetic agent identification and respiration rate) ventilation (airway pressure, volume and flow) and gas exchange (Oxygen Consumption VO2, Carbon Dioxide production VCO2, Respiratory Quotient RQ, and Energy Expenditure, EE, Gas exchange monitoring is not indicated in the presence of N2O+O2 mixtures), status of hospital patients during magnetic resonance scanning.

The NIBP measurement is indicated for patients who weigh 5kg (11 lb) and up. The MRI Monitor with L-CANE05 or L-CANE05A software is also indicated for documenting patient care related information.

The MRI Monitor with L-CANE05 or L-CANE05A software, module options N-PSNGV, N-PSNG, N-SNGV, N-SNG, N-PSN, N-SN, E-MRICAiOVX, E-MRICAiOV, E-MRICAiO, E-MRICO and accessories is indicated for use in the MR environment up to 300 Gauss with static magnets up to 3.0 Tesla. SpO2 and ECG monitoring is indicated only with accessories (OXY-FMR, OXY-WMR, 897986 (ECG cable, AAMI) and 897987, ECG Cable, IEC) specifically designed for the MR environment.

The MRI Monitor with L-CANE05 or L-CANE05A software is indicated for use by qualified medical personnel only.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

B Zimmerman

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K062324